Remarks/Arguments:

Applicants wish to thank Supervisory Patent Examiner (SPE) Sreenivasan Padmanabhan and Examiner Leonard M. Williams for the courteous consideration rendered their representatives—Dominique Thibaud, Dr. Vet., Ceva Sante Animale, and the undersigned attorney of record—during an interview at the Patent and Trademark Office on June 4, 2006 ("the interview"). The interview involved discussions of all rejections of record, proposed claim amendments that addressed the rejection of record, and further prosecution of the subject application following final rejection. Details of these discussions are integrated into applicants' remarks presented below.

Claim12, currently amended, and claims 13-20, previously presented, are pending.

Claims 1-11 are canceled, without prejudice or disclaimer.

Claim 12 is amended, hereby, in order to more clearly define the instant invention. Specifically, there are two amendments to the claim: (1) the claim preamble is changed from"Process for treating lameness that appears during osteoarthrosis" (emphasis added) to "Process for treating lameness caused by osteoarthrosis" and (2) the proviso "not suffering from arthritis" (emphasis added) is deleted. Neither amendment is substantive.

As to the first amendment—reciting "caused by" in place of "that appears during"— the original language and the replacement language have the same meaning, i.e., as necessarily interpreted in light of the specification. *In re Zletz,* 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its

relation to the prior art"). For example, according to the present specification (page 1, line 13 – page 2, line 9) (emphasis added):

> Lameness results . . . from the appearance of painful lesions on the bone structure, the cartilages . . . generally associated with . . . an osseous component which is the result of a change in the bone architecture and/or in the bone growth cartilages at the site of the lameness . . . for example, erosions of the cartilaginous surfaces . . . The invention is directed towards providing a process for treating lameness with an osseous component and/or with an articular component . . . Lameness with an osseous, articular or osteoarticular component appear . . . during osteoarthrosis.

As to the second amendment to claim 12, deleting the proviso "not suffering from arthritis" does not change the scope of the claims as interpreted by the examiner—since "The examiner is . . . not giving weight to the '. . . not suffering from arthritis . . .'" language (Office Action, page 6). Moreover, the purpose of deleting the exclusionary language, as explained during the interview, is not to broaden the claims; but, rather, the amendment is presented for the purpose of overcoming the rejection under §112, ¶2 (discussed below), and to advance prosecution, thereby.

Accordingly, both of the amendments to claim 12 are directed to form, only, effecting no substantive change (neither amendment has an effect on claim scope). They are presented, nevertheless, in a good faith effort to advance prosecution, in view of the discussions with the examiners during the interview, as explained more fully, below.

All the rejections in the final Action, i.e., under §112, ¶2, §102(b), and §103(a), turn on the definition of "arthritis" and its relationship to "osteoarthrosis"—as described and claimed in the subject application as originally filed. Therefore, the purpose of the interview was to resolve issues arising due to the terminology "arthritis" and "osteoarthrosis"—by interpreting these terms in view

of the subject application (itself), the prosecution history, and the prior art, i.e., as they would be interpreted by the person of ordinary skill in the art.

Claim 12 was rejected under 35 USC 112, 2nd ¶, for allegedly being indefinite. Reconsideration is requested.

According to the statement of rejection, the proviso to treating humans and animals "not suffering from arthritis" renders the claim indefinite. The rejected claim is directed to treating "osteoarthrosis" sufferers. The rejection maintains that the recited "osteoarthrosis" is a form of the recited "arthritis" and—as so interpreted—the claim excludes the same individuals that it treats.

As set forth in the previous response, the rejection cannot be maintained. The rejection is incorrect, since it is based on an unreasonable claim interpretation, i.e., an interpretation that would not be given the claim by one of ordinary skill in the art. *In re Smythe*, 178 USPQ 279, 286 (CCPA 1973). *In re Geerdes*, 180 USPQ 789, 793 (CCPA 1974). Claim terms need not be "conventional," since a patent applicant is entitled to be his own lexicographer. *In re Castaing*, 166 USPQ 550 (CCPA 1970). In fact, the specification and claims "may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings." *Hormone Research Foundation, Inc. v. Genentech, Inc.*, 15 USPQ2d 1039, 1043 (Fed. Cir. 1990) (emphasis added).

Nevertheless, during the interview, applicants' representatives proposed (to the examiners) deleting the proviso from the claims and, thereby, rendering the rejection moot. In other words, the basis of the rejection—excluding "arthritis" sufferers from a process that treats "osteoarthrosis" sufferers—no longer exists. Cancelling the proviso is in no way an admission against applicants'

interests. On the contrary, applicants maintain that a patentable distinction exists between the present claims and the treatment of "arthritis" (as defined in the context of the subject application).

The examiners indicated that the proposed amendment might resolve the issue, i.e., overcome the §112, ¶2, rejection. However, they wanted to reserve final judgment pending receipt of the amendment in writing (on the record) and giving the amendment more thorough consideration.

Accordingly, applicants submit that deleting the proviso "not suffering from arthritis" from the claims, in accordance with instant amendment, overcomes the rejection under §112, ¶2, i.e., by rendering the rejection moot. Withdrawal of the rejection appears to be in order.

Claims 12, 15, 17, 18, and 20 stand rejected under 35 USC 102(b) as being allegedly anticipated by US 4876248 (Breliere) and in view of applicants' alleged admission. Claims 13, 14, 16, and 19 stand rejected under 35 USC 103(a) as being allegedly unpatentable over Breliere in view of US 5488041 (Barbier). Reconsideration of the rejections under §102(b) and §103(a) is requested, in view of the amendments to the claims, effected hereby, in conjunction with the remarks, in view of the discussions during the interview.

Applicants have acknowledged that "osteoarthrosis" is synonymous with osteoarthritis. Hereafter, the terms are used interchangeably.

Rejections overcome by amendment

First of all, the rejected claims are rewritten, hereby, to expressly recite that the invention process is for "treating lameness caused by osteoarthrosis" (claim 12) (emphasis added). This amendment is presented in view the discussions during the interview.

During the interview, the examiners indicated that a salient factor in maintaining the rejections is that "treating lameness that occurs during osteoarthritis" (emphasis added), as recited in the rejected claims, does not require that "osteoarthritis" be the cause of the "lameness" being treated. In other words, as interpreted by the examiners, "treating lameness that occurs during osteoarthrosis" means only that "lameness" and "osteoarthrosis" be occurring simultaneously; and, so, other pathological conditions, such as arthritis, could be the cause of the lameness. Since Breliere teaches the treatment of arthritis by using the same compounds used in the treatment method of the rejected claims, and "treating lameness that occurs during osteoarthrosis" (allegedly) reads on treating lameness caused by, *i.a.*, arthritis, the rejected claims allegedly read on Breliere.

The examiners' concern expressed during the interview apparently reflects the *inherency* argument set forth in the statement of rejection, part of which states (final Action, paragraph bridging pages 8 and 9) (emphasis added):

> As a portion of the patient population treated for arthritis would have some degree of lameness and as the compounds disclosed by Breliere et al. are identical to the compounds in the currently claimed method of treating lameness that appear during osteoarthrosis the lameness is inherently treated by the compounds of Breliere et al. in the general treatment of inflammation and in particular arthritis.

And, applicants maintain that the inherency argument cannot be sustained, as set forth in the remarks to their previously filed amendment.

Nevertheless, in a good faith effort to advance prosecution, applicants changed the language "treating lameness that occurs during osteoarthrosis" to "treating lameness caused by osteoarthrosis."

Breliere's teachings are strictly limited to the treatment of rheumatic forms of arthritis (as explained in detail below). Breliere neither teaches nor suggests anything whatsoever concerning osteoarthritis.

Accordingly, applicants submit that amending the rejected claims to recite "treating lameness caused by osteoarthrosis," by itself, overcomes the rejection under §102(b), i.e., given the examiner's finding that "treating lameness that occurs during osteoarthrosis" does not exclude treating lameness caused by, e.g., rheumatoid arthritis, which is treated as disclosed in Breliere. Furthermore, applicants submit that overcoming the rejection under §102(b) overcomes the rejection under §103(a), since the §103(a) rejection expressly relies on the rejection under §102(b). The §103(a) rejection states that the rejected claims are "unpatentable over Breliere et al. as applied to claims 12, 15, 17-18, and 20 [in the §102(b) rejection] above" (final Action, page 9). As the rejection under §102(b) falls, so falls the rejection under §103(a).

Cited references neither teach nor suggest the claimed invention

Secondly, besides overcoming the §102(b) and §103(a) rejections by amendment, the rejected (and present) claims are patentable over the cited references for the reasons discussed during the interview. As indicated, above, the purpose of the interview was to resolve issues arising due to the terminology "arthritis" and "osteoarthrosis"—as used in the context of the subject application. As further indicated above, the rejections under §102(b) and §103(a) turn on resolution of these issues. Accordingly, as agreed during the interview, applicants provide the following précis of the interview discussions in this respect.

In accord with the interview's purpose, Dr. Thibaud—as an expert in the field—explained applicants' position with respect to

- the differences between a degenerative joint disease—such as osteoarthritis— and a rheumatic joint disease—such as rheumatoid arthritis—,
- interpretation of the teachings of Breliere, with regard to anti-inflammatory properties of the disclosed compounds and their disclosed use to treat "arthritic conditions" (Breliere column 23, line 15), by one of ordinary skill in the art, and
- interpreting the term "arthritis," as used in the context of the subject application, and its relationship to osteoarthritis, as described and claimed in the subject application.

As stated in the interview summary (page 5) the term "arthritis" is used to cover over 100 joint diseases in humans. Chronic forms of these diseases afflict 42 million Americans.

Joint diseases in humans and animals are exemplified by:

osteoarthritis ("OA") = osteoarthrosis = degenerative joint disease,

- rheumatoid arthritis ("RA"),
- infectious arthritis,
- gout,
- ankylosing pondylitis, and
- systematic lupus erythematosus.

OA and RA are the two most common forms of joint disease in humans.

Osteoarthritis, originally known as "degenerative joint disease," is a form of mechanical joint disease, i.e., mechanical forces acting on the joint induce its degeneration. The primary symptom of osteoarthritis is pain, which can lead to lameness, e.g., when the affected joint is the knee.

Rheumatoid arthritis, as opposed to osteoarthritis, is (1) a form of inflammatory joint disease and (2) an autoimmune disease. The body's own defense mechanism attacks the cell lining inside the joint, causing inflammation with resulting pain, stiffness, and loss of joint function. Eventually, rheumatoid arthritis leads to permanent disfigurement of the affected joint.

The differences between inflammatory arthritides and mechanical arthritides are well documented in the literature, as exemplified by "Inflammatory vs mechanical arthritis," *Health 24 – Joint pain/Arthritis All about joints*, online at http://www.health24.com/medical/Condition_centres/777-792-816-1785,15983.asp (copy attached). The American College of Rheumatology discusses the differences in "Recommendation for the medical management of osteoarthritis of the hip and knee," *Arthritis & Rheumatism, 43*, 2000, 1905-1915. As set forth in the article (emphasis added),

> Unlike the case with rheumatoid arthritis (RA) and other inflammatory arthritides, inflammation, if present, [in osteoarthritis] is usually mild and localized to the affected joint.

The differences are also discussed in "Osteoarthritis: Joint anatomy, physiology and pathobiology," *Vet Clin North Am Small Anim Pract, 27*, 699-723, 1997, i.e. (emphasis added):

> The presence or absence of inflammation has generated controversy regarding appropriate terminology. The terms osteoarthrosis or degenerative joint disease . . . allows communication of a clinical syndrome that is distinguished from inflammatory arthritis . . . typically associated with an influx of inflammatory cells and is most appropriately associated with conditions having immune-mediated or infectious etiologies. Rheumatoid arthritis is a classical example of a primary

> immune-mediated systematic condition that is associated with immune cell invasion of periarticular tissues, destruction of bone and erosive change of articular cartilage.

Accordingly, a differential diagnosis of osteoarthrosis—in both humans and animals—involves, *i.a.,* elimination of inflammation as a primary characteristic. As set forth in *Lameness in the Horse*, 2002, 572-591 (emphasis added):

> Osteoarthritis has been defined as an essentially non-inflammatory disorder of movable joints, characterized by degeneration and loss of articular cartilage and the development of new bone on joint surfaces and margins.

Osteoarthritis can not be mistaken for other arthritic conditions. Physicians and veterinarians must—and easily can—diagnose osteoarthritis, differentially; e.g., from inflammatory types of arthritis, such as rheumatoid arthritis, on the basis of clinical onset, symptomatology, localization, and nature of tissue lesions. The U.S. Food and Drug Administration (FDA) has, even, published one set of guidelines for developing drugs to treat osteoarthritis and a separate set of different guidelines for developing drugs to treat rheumatoid arthritis.

Osteoarthritis is recognized in the art as being totally different from rheumatoid arthritis. Osteoarthritis is characterized by degeneration of the articular cartilage (covering the bone surfaces that meet in the joint and, thereby, separating the bone surfaces from one another) and, so, resulting in direct bone-to-bone contact in the joint, pain being the primary symptom (and, when, e.g., the knee joint is affected, pain-induced lameness, i.e., limping); on the other hand, rheumatoid arthritis is an autoimmune disease, characterized by autoimmune-induced inflammation of the synovial membrane and resulting swelling of the joint which, by itself, if the knee joint is affected, causes lameness, eventually resulting in permanent disfigurement of the diseased joint. Pain is a common

factor in both osteoarthritis and rheumatoid arthritis, therefore, analgesics are used to treat the pain in both cases; however, this is no different than use of analgesics to treat pain for any reason; and, therefore, it does not suggest that a compound shown to be effective in treating rheumatoid arthritis, itself, would be effective in treating osteoarthritis, itself (i.e., affect the nervous system, not the diseased joint).

US4956381 (cited in the IDS filed concurrently, herewith), column 15, lines 20-33, relies on pain relief as the measure of efficacy in testing compounds for the treatment of osteoarthritis and rheumatoid arthritis. US6177467 (cited in the IDS filed concurrently, herewith) discloses use of a single compound—N-L-α-aspartyl-L-phenylalanine 1-methyl ester (APM)—and its derivatives in the treatment of osteoarthritis and rheumatoid arthritis, based on unique effects of APM: (a) the treatment of osteoarthrosis, because "APM has been found to produce a decrease in bone resorption and an increase in bone mass" (US '467, column 5, lines 49-51); (b) the treatment of rheumatoid arthritis, because "APM has been shown to interfere with the effects of TNF-α in the inflammatory process. Particularly, in rheumatoid arthritis, APM has been shown to reduce the pathological arthritic effects of TNF-α" (US '467, column 5, lines 51-55). Relevance of US '467, thus, is limited to a single compound having three unique effects, i.e., (1) decreasing bone resorption, (2) increasing bone mass, and (3) interfering with the effects of TNF-α in the inflammatory process.

Applicants do acknowledge that compounds that have been characterized as non-steroidal anti-inflammatory drugs (NSAIDs) have been prescribed for the treatment of osteoarthritis. However, the use of NSAIDs for treating osteoarthritis is controversial (*BMJ*,

doi:10.1136/BMJ.38273.626655.63 (published November 23, 2004), (copy attached). Moreover, while characterized as non-steroidal anti-inflammatory drugs, studies involving their use in treating osteoarthritis are based on pain relief (e.g., the previously cited *BMJ* article). As set forth in the subject application (page 6, lines 29-32):

> The medical treatments most usually prescribed for lameness are directed towards pain relief; this is the case, for example, for treatments with non-steroidal anti-inflammatory medicines.

Applicants are unaware of any studies using NSAIDs to treat osteoarthrosis that directly measure inflammation.

In comparing the teachings of Breliere with the rejected (and present) claims, both Breliere and the claims must be interpreted through the eyes of the person of ordinary skill in the art. Accordingly, the knowledge of the art—as explained and evidenced, above—reflects the knowledge of that person skilled in the art and, accordingly, must be taken into consideration.

First, in interpreting Breliere, in particularly usefulness of the disclosed compounds "for the treatment of conditions due to inflammatory phenomena and in particular for the treatment of arthritic conditions" (Breliere, column 23, lines 13-16), it is clear that Breliere's teachings (properly interpreted) are limited to usefulness of the disclosed compounds for the treatment of inflammatory arthritic conditions, such as rheumatoid arthritis.

The bulk of Breliere's disclosure is directed to the anti-inflammatory properties of the disclosed compounds. Concerning disclosure related to "rheumatic conditions"—based on the "In Vitro Study"—and disclosure related to treating human "rheumatoid arthritis" based on results

obtained in rat-model tests—"In Vivo Study"—Breliere teaches (column 20, line 65–column 21, line 10, column 22, lines 20-23, and column 23, lines 11-19) (emphasis added):

> The compounds according to the invention are advantageously used as anti-inflammatory and anti-rheumatic drugs and their pharmacological properties have been demonstrated as follows.
>
> IN VITRO STUDY
>
> The in vitro study is based on the fact that chondrocytes in a culture secrete neutral proteinases after stimulation by a factor synthesized by peritoneal macrophages or by the mononuclear cells of the blood.
>
> The involvement of this type of stimulation in rheumatic conditions has been clearly demonstrated in numerous publications.
>
> The principle of the test hence consists in studying the secretion of neutral proteinases by stimulated chondrocytes treated with the products in comparison with the secretion of the stimulated but untreated chondrocytes. . . .
>
> IN VIVO STUDY: Adjuvant arthritis
>
> The injection of Mycobacterium into the rat causes a polyarthritis which in certain respects resembles human rheumatoid arthritis.
>
> Procedure
>
> A suspension of Mycobacterium tuberculosis (0.4 mg per 0.05 ml of medicinal paraffin) is injected intradermally into the tail of male Sprague-Dawley rats having an average weight of 150 g.
>
> After 15 days, the animals exhibiting the most marked arthritis symptoms are selected. . . .
>
> Moreover, the products according to the invention are of low toxicity.
>
> They can be used in human therapy for the treatment of conditions due to inflammatory phenomena and in particular for the treatment of arthritic conditions. In particular, the compounds according to the invention can be used in the treatment of rheumatoid polyarthritis.

Accordingly, "arthritic conditions" are defined as a species of "inflammatory phenomena" exemplified by "rheumatoid polyarthritis" (rheumatoid arthritis affecting multiple joints). In other

words, Breliere defines "arthritic conditions" such that it excludes osteoarthritis—a non-inflammatory, a mechanically induced degenerative joint disease, completely different from rheumatoid arthritis, as explained above.

Breliere patentee Jean Breliere, *i.a.*, published several papers in the mid-80s reporting the results obtained using the model of adjuvant arthritis in the rat, i.e., the same rat model used in Breliere's "In Vivo Study." As Dr. Thibaud pointed out during the interview, the results reported in these papers are always interpreted as being supportive of a potential efficacy of a particular compound, tiludronate (SR 41319), to treat rheumatoid arthritis, only, i.e., they are not supportive of potential efficacy to treat mechanical/degenerative joint diseases such as osteoarthritis. One of these papers, "Recent advances in the field of remission-inducing drugs for arthritis," *Advances in Inflammation Research, 10*, 1986, 381-384 (copy attached), states (page 383):

> In conclusion, these data evoke that SR 41319 has all the pre-requisites for being taken into consideration as a candidate drug for the treatment of RA [rheumatoid arthritis]. Clinical investigations are on the way;

and "Studies of the chronic phase of adjuvant arthritis: effect of SR 41319, a new diphosphonate," *Annals of Rheumatic Diseases, 45*,1986, 67-74 (copy attached), states (page 67, Summary):

> We conclude that SR 41319 may be a potentially useful drug for the treatment of rheumatoid arthritis.

The (attached) papers show that a Breliere patentee (Jean Breliere) could not have intended the disclosed rat-model "In Vivo Study" results to teach or suggest utility beyond the inflammatory type of joint disease exemplified by rheumatoid arthritis.

In view of the foregoing, one skilled in the art would have defined "arthritic conditions" in the context of Breliere's teachings

> products according to the invention . . . can be used in human therapy for the treatment of conditions due to inflammatory phenomena and in particular for the treatment of arthritic conditions. In particular, the compounds according to the invention can be used in the treatment of rheumatoid polyarthritis

to mean inflammatory arthritic conditions, which does not meet (i.e., excludes) the treatment of osteoarthritis—a non-inflammatory, mechanical/degenerative bone disease. While claims are to be given their broadest reasonable interpretation during prosecution, the definition of a claim limitation given by the Examiner cannot be different than would be given by one of ordinary skill in the art. *In re Cortright*, 49 USPQ2d 1464 (Fed. Cir. 1999).

In connection with interpreting the subject application, as Dr. Thibaud explained during the interview, the origins of "arthritis" and "osteoarthrosis" in the French language priority application are important. The French medical term "arthrite," literally translated "arthritis," is generally understood to define the autoimmune disease rheumatoid arthritis, characterized by inflammation of the soft tissue in the joints (e.g., knees) that leads to swelling and (ultimately) irreversible deformity of the affected joint.

On the other hand, as Dr. Thibaud explained, the French medical term "ostéoarthrose"—literally translated "osteoarthrosis"—defines the disease characterized by non-inflammatory, mechanically induced degeneration of the articular cartilage in a joint, causing bone-to-bone contact and resulting pain. Degeneration of the articular cartilage is caused by the wear-and-

tear of mechanical forces on the affected joint over a number of years, which is why the disease is typically a result of the aging process.

Therefore, as Dr. Thibaud stated, in French "arthritis" (arthrite) and "osteoarthrosis" (ostéoarthrose) are mutually exclusive. When the French priority application was translated into the English version, for filing in the PTO, "arthrite" was translated "arthritis" and "ostéoarthrose" was translated "osteoarthrosis," i.e., intending to have the same, mutually exclusive definitions as their French counterparts.

Furthermore, it is clear from the subject application, itself, that "arthritis" and "osteoarthrosis" are mutually exclusive. "Arthritis" is not used in any generic sense to cover both rheumatoid arthritis and osteoarthritis. This is evidenced in the context of the rejection under §112, ¶2, i.e., were "arthritis" defined generically, the arthritis disclaimer would render the claims indefinite. On the other hand, when"arthritis" is correctly interprested—as used in the context of the subject application, i.e., accorded the meaning intended by applicants, *Castaing, supra*, and *Hormone Research Foundation, Inc., supra*—to mean the inflammatory type of joint disease exemplified by rheumatoid arthritis, the rejected claims comply with the requirements of §112, ¶2. The meaning accorded claim terminology by the PTO cannot conflict with the meaning accorded in the specification, which meaning must be used by the PTO in construing the claims for comparison with the prior art. *In re Zletz,* 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

The skilled artisan would have understood "arthritis"—as the term is used in the context of the subject application—to denote inflammatory arthritis, e.g., rheumatoid arthritis. As explained, above, each of the diseases are differently characterized in the art:

- "rheumatoid arthritis" is characterized by an autoimmune-induced inflammation of the soft tissue, with resulting swelling and, ultimately, irreversible deformity of the inflamed joint's anatomical structure.

- "osteoarthritis"—a mechanical/degenerative joint disease—is characterized by deterioration of the articular cartilage over time, due to mechanical forces acting on the joints. Pain is the symptom of osteoarthritis, although why is uncertain. Any inflammation associated with the disease is caused by factors other than the disease, itself.

- in general, drugs that are known to be clinically effective in the treatment of rheumatoid arthritis (except for treating pain, per se) are not known to be clinically effective in the treatment of osteoarthritis. The United States Food and Drug Administration (FDA), while having approved drugs for the treatment of arthritis, has not approved any drug for treating osteoarthritis, *per se*. In fact, no drug has been accepted by the medical community as clinically effective in the treatment of osteoarthritis.

"Osteoarthrosis" (i.e., osteoarthritis) and inflammatory arthritis (i.e., the meaning of "arthritis" in the context of the subject application) are completely different pathological conditions, similar in that they both cause pain and affect some—but not all—of the same joints in the body.

Otherwise, they are characterized by differences, *i.a.*, in etiology, anatomical effect, and treatment. Accordingly, the differences between "arthritis" and "osteoarthrosis," as used in the specification and claims of the subject application, would have been readily appreciated by the skilled artisan, such that the skilled artisan would not have considered it obvious to use a drug to treat "osteoarthrosis" based on successful use of the drug in treating inflammatory arthritis (i.e., the meaning of "arthritis" in the context of the subject application).

Relying primarily on *Steadman's Medical Dictionary*, 27th ed., the statement of rejection (Office Action page 4) argues "the definition of osteoarthritis clearly indicates that it is an 'arthritis.'" Accordingly, the statement of rejection maintains that the subject application is confusing, since it uses the term "arthritis" to describe a disease different from "osteoarthrosis." However, the apparent confusion is caused by the interpretation given in the statement of rejection, which is incorrect.

When properly (and reasonably) construed, the subject application causes no confusion by using the term "arthritis" to identify a disease different from "osteoarthrosis," even though the resulting definition of "arthritis" appears to conflict with a dictionary definition, e.g., the definition in *Steadman's Medical Dictionary*, relied on in the statement of rejection.

When the definition of a claim term according to the "patent [specification] and the prosecution history" conflicts with a definition of the term used "in the field of the invention," the correct interpretation is that according to the specification and the prosecution history. *Hoechst Celanese Corp. v. BP Chemicals Ltd.*, 38 USPQ2d 1126, 1129 (Fed. Cir. 1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by persons

experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning" [emphasis added]).

Moreover, a claim is not indefinite, under §112, ¶2, merely because there are different "dictionary definitions that support" contrasting meanings of claim terms. *Hoechst Celanese Corp.*, 38 USPQ2d at 1129-1130. Further yet, when one meaning would "exclude" the inventor's "preferred embodiment" from the claim, and the other meaning would include the inventor's preferred embodiment in the claim, the correct interpretation is that which would include the inventor's preferred embodiment. *Hoechst Celanese Corp.*, 38 USPQ2d at 1130 ("it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way").

With respect to the rejection under §102(b), for anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The absence from a prior art reference of a single claim limitation negates anticipation. *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

As explained, above, Breliere does not meet the limitation to the treatment of "lameness" caused by "osteoarthrosis" (osteoarthritis) as recited in the rejected (and present) claims. Accordingly, a limitation on the claims being absent from Breliere, anticipation by the reference is negated. *Kolster Speedsteel A B, supra.* Withdrawal of the rejection under §102(b) appears to be in order.

In connection with the rejection under §103(a), to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

Barbier provides nothing that cures the fatal deficiency in Breliere, i.e., failure to meet the limitation to treating osteoarthritis-induced lameness. Barbier merely discloses a method for promoting bone repair following fracture or bone surgery. The reference neither teaches nor suggests—expressly or inherently—any beneficial activity on osteoarthritis-induced lameness. The person of ordinary skill in the art seeking to treat a *noninflammatory* condition or disorder, such as osteoarthritis-induced lameness, would not have been motivated by Barbier to use bisphosphonic acid derivatives.

Accordingly, the limitation to the treatment of "lameness" caused by "osteoarthrosis" (osteoarthritis) is not supported by either of the cited references—Breliere and Barbier—taken alone or together. Since "the cited references do not support each limitation" of the rejected (and present) claims, the rejection is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008. Withdrawal of the rejection under §103(a) appears to be in order.

Additionally, applicants incorporate herein, by reference, the remarks addressing the §102(b) and §103(a) rejections set forth in their previous amendment (filed October 19, 2005), pages 10-16; however, reconsideration of the previously filed remarks is requested in view of the presentation made by applicants' representatives and the related discussion that ensued between applicants' representatives and the examiners, during the interview.

In connection with the previously filed remarks, note is taken of the counter argument that prior art treatments using bisphosphonic acid derivatives would have inherently treated osteoarthritis-induced lameness. The counter argument, in effect, treats the teachings of the presently claimed invention—a clinical effect of using bisphosphonic acid derivatives—as if the clinical effect were part of the prior art, which it is not. The rejection confuses an unrecognized clinical effect—treating osteoarthritis-induced lameness—with an inherent clinical effect. For the treatment of osteoarthritis-induced lameness using bisphosphonic acid derivatives to be inherent in the art it must have been recognized, i.e., known, in the art. *In re Shetty*, 195 USPQ 753, 747 (CCPA 1977), involved method claims for the new use—appetite suppressant—of known compounds. In finding the claims patentable, *Shetty* held:

> Prior to appellant's disclosure, none of the . . . compounds in any of the references . . . suggested the use . . . for curbing appetite.

Likewise, the rejected (and present) claims are patentable since neither cited reference "suggested the use" of the bisphosphonic acid derivatives for treating osteoarthritis-induced lameness.

Barbier discloses a method for promoting bone repair following fracture or bone surgery. The reference neither teaches nor suggests—expressly or inherently—any beneficial activity on osteoarthritis-induced lameness. The person of ordinary skill in the art seeking to treat a *noninflammatory* condition or disorder, such as osteoarthritis/arthrosis, would not have been motivated by Barbier to use bisphosphonic acid derivatives.

Accordingly, nothing in the secondary reference Barbier cures these fatal deficiencies of Breliere in meeting each limitation on the present claims. Since each limitation on the rejected claims is not supported by the cited references, the rejection under §103(a) is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008. Withdrawal of the rejection under §103(a), therefore, appears to be in order.

2ND Request for Examiner's Initialed Form PTO 1449

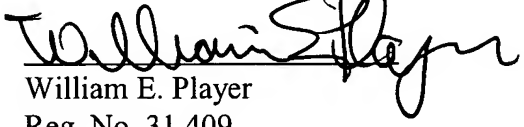
In their paper filed October 19, 2005, in the PTO, applicants requested that the PTO return the Forms PTO 1449 submitted with the IDS filed November 28, 2003, initialed by the Examiner to show that the references cited, thereon, were considered by the Examiner during prosecution of the subject application. The final Office Action (Summary page) was marked to indicate that the initialed Forms PTO 1449 were attached, but they were not.

Accordingly, it is again requested that the PTO return the submitted Forms PTO 1449, initialed by the Examiner to show that the references cited, thereon, were considered by the Examiner during prosecution of the subject application.

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By 

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